

REDACTED VERSION

Jay P. Lefkowitz
John P. Del Monaco
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
Telephone: (212) 446-4800
Facsimile: (212) 446-4900
lefkowitz@kirkland.com
jdelmonaco@kirkland.com

Douglas J. Kurtenbach
Nader R. Boulos
KIRKLAND & ELLIS LLP
300 North LaSalle Drive
Chicago, IL 60654
Telephone: (312) 862-2000
Facsimile: (312) 862-2200
douglas.kurtenbach@kirkland.com
nader.boulos@kirkland.com

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

FERA PHARMACEUTICALS, LLC,

Plaintiff,

- against -

AKORN, INC.; SEAN BRYNJELSEN; and
MICHAEL STEHN,

Defendants.

Case No. 12-cv-07694-LLS

ECF Case

COUNTERCLAIMS OF AKORN, INC.

AKORN, INC.,

Counterclaim-Plaintiff,

- against -

FERA PHARMACEUTICALS, LLC, ALFERA
PHARMACEUTICALS, LLC, FERANDA, LLC,
BACI 007, LLC, FERA HOLDINGS, LLC,
PERRIGO COMPANY OF TENNESSEE, and
PERRIGO COMPANY PLC,

Counterclaim-Defendants.

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Pursuant to Federal Rules of Civil Procedure 13, 19, and 20, the Court's October 24, 2014 Order granting leave to amend (Dkt. No. 35), and the Court's January 8, 2014 Order allowing the filing of counterclaims (Dkt. No. 43), Counterclaim-Plaintiff Akorn, Inc. ("Akorn") hereby asserts its counterclaims against Counterclaim-Defendants Fera Pharmaceuticals, LLC, Alfera Pharmaceuticals, LLC, Feranda, LLC, Baci 007, LLC, Fera Holdings, LLC (collectively, "Fera") and Counterclaim-Defendants Perrigo Company of Tennessee and Perrigo Company plc (collectively, "Perrigo"), and alleges as follows:

INTRODUCTION

1. In June 2013, Fera and Perrigo attempted, conspired, and ultimately implemented a scheme to monopolize the U.S. market for Bacitracin ophthalmic ointment ("Bacitracin"), with the specific aim of disrupting Akorn's imminent entry into that market. At the time, Fera was the only company with an FDA-approved ANDA (Abbreviated New Drug Application) actively selling Bacitracin in the U.S., Akorn was on the verge of obtaining FDA approval of its ANDA so that it could enter the market with its own Bacitracin, and non-party [REDACTED] was and remains the only supplier of the essential raw material—the active pharmaceutical ingredient ("API")—necessary to manufacture any Bacitracin product, including Akorn's. [REDACTED] had provided Akorn a Letter of Authorization ("LOA") confirming that it would supply Akorn with its sterile Bacitracin API for its ANDA, and this letter was submitted with Akorn's ANDA application.

2. In the months leading up to June 2013, Fera had tried and failed to sell its entire product portfolio, including its rights to its Bacitracin product, to two larger pharmaceutical companies. [REDACTED]

[REDACTED]

[REDACTED]

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3. Subsequently, Fera and Perrigo illegally conspired to create that elusive exclusivity for Bacitracin through two related contractual agreements, paving the way for Perrigo to acquire Fera's product portfolio. On June 14, 2013, Fera and Perrigo entered into an Asset Purchase Agreement ("APA"), pursuant to which Perrigo acquired the rights to a portfolio of Fera's products, including Bacitracin, for an upfront payment of \$93 million [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

4. Fera and Perrigo engaged in a pattern of conduct intended to cause [REDACTED] to cut off its longstanding supply relationship with Akorn. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

5. [REDACTED] ultimately relented, [REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

6. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The LOA revocation had its desired effect: the FDA promptly rescinded its approval of Akorn's ANDA in early 2014.

7. Fera and Perrigo have reaped illicit profits through this anti-competitive, monopolistic scheme. Conversely, Akorn and U.S. consumers have been significantly harmed. The illegal agreements set Akorn back by many months, if not years, in its efforts to enter the market, resulting in millions of dollars of lost sales volume and lost profits. The absence of competition has adversely affected consumers, who have been forced to pay artificially inflated prices for Bacitracin.

8. Akorn asserts that Fera and Perrigo's actions violated Sections 1 and 2 of the Sherman Antitrust Act. In addition, Akorn asserts a claim for tortious interference with business relations against Fera and Perrigo, based on their improper, defamatory, and illegal acts that caused [REDACTED] to cut off its longstanding business relationship with Akorn. To remedy the harms

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caused by Fera and Perrigo's actions, Akorn seeks an injunction preventing continuation of these violations of law, as well as compensation for the damages to Akorn's business that resulted from Fera and Perrigo's actions.

PARTIES

9. Counterclaim-Plaintiff Akorn is a Louisiana Corporation with its principal place of business at 1925 West Field Court, Lake Forest, Illinois 60045.

10. Counterclaim-Defendant Fera Pharmaceuticals, LLC is a limited liability company organized under the laws of New York with its principal place of business at 134 Birch Hill Road, Locust Valley, New York 11560.

11. Counterclaim-Defendant Alfera Pharmaceuticals, LLC is a limited liability company organized under the laws of New York with its principal place of business at 134 Birch Hill Road, Locust Valley, New York 11560.

12. Counterclaim-Defendant Feranda, LLC is a limited liability company organized under the laws of New York with its principal place of business at 134 Birch Hill Road, Locust Valley, New York 11560.

13. Counterclaim-Defendant Baci 007, LLC is a limited liability company organized under the laws of New York with its principal place of business at 134 Birch Hill Road, Locust Valley, New York 11560.

14. Counterclaim-Defendant Fera Holdings, LLC is a limited liability company organized under the laws of New York with its principal place of business at 134 Birch Hill Road, Locust Valley, New York 11560.

15. Fera Holdings, LLC is the sole member of Counterclaim-Defendants Fera Pharmaceuticals, LLC, Alfera Pharmaceuticals, LLC, Feranda, LLC, and Baci 007, LLC. [REDACTED]

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[REDACTED]

[REDACTED]

16. Counterclaim-Defendant Perrigo Company of Tennessee is a corporation organized under the laws of Tennessee with its principal place of business at 515 Eastern Avenue, Allegan, MI 49010.

17. Counterclaim-Defendant Perrigo Company plc is a corporation organized under the laws of Ireland with its principal place of business at 515 Eastern Avenue, Allegan, MI 49010. Perrigo is one of the world's largest manufacturers of over-the-counter pharmaceutical products. Perrigo operates around the globe with markets and operation centers located in, among other places, the United States, Israel, Mexico, the United Kingdom, India, China and Australia. Perrigo regularly and systematically conducts business in this District, including through a manufacturing facility in Bronx County, New York. [REDACTED]

[REDACTED]

[REDACTED]

18. Perrigo Company of Tennessee is a wholly-owned subsidiary of Counterclaim-Defendant Perrigo Company plc. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

JURISDICTION AND VENUE

19. Akorn brings these counterclaims under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, to obtain damages and injunctive relief against all Counterclaim-Defendants. Akorn brings its counterclaim for tortious interference under state law.

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20. This Court has jurisdiction under 28 U.S.C. §§ 1331 and 1337 over Akorn's claims arising under Sections 1 and 2 of the Sherman Act, and jurisdiction over all claims under 28 U.S.C. § 1332 because there is complete diversity between Counterclaim-Plaintiff and Counterclaim-Defendants. In addition, this Court has supplemental jurisdiction over Akorn's state law claim under 28 U.S.C. § 1367. Akorn's state law claim is so related to its claims under the federal antitrust laws that it forms part of the same case or controversy.

21. Venue is proper in this District because this is where Fera laid venue in its initial pleading, and a substantial portion of the activities giving rise to the counterclaims occurred in this District, [REDACTED]. In addition, interstate trade and commerce involved and affected by the alleged violations of law was and is caused in part in this District. The acts complained of have had, and will have, substantial anti-competitive effects in this District. Venue is therefore proper in this District under 28 U.S.C. § 1391 and 15 U.S.C. § 15.

FACTUAL ALLEGATIONS

I. Akorn Develops Bacitracin Ointment A Decade Prior To Fera's Acquisition of Bacitracin Rights.

22. Akorn's history reaches back more than a half century, during which it has developed, marketed, and manufactured hundreds of generic and branded pharmaceutical products. In 1999 and 2001, Akorn developed batches of Bacitracin Ophthalmic Ointment in anticipation of seeking approval from the U.S. Food and Drug Administration to market and sell Bacitracin in the U.S. Those batches were created using an API—an essential raw material in the manufacture of generic ointments like Bacitracin—that Akorn acquired from [REDACTED] [REDACTED]

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████████████████████ The identity of the API supplier and the ability to reference its drug master file is a required element in the ANDA application.¹

23. In or around 2001, based on the exhibit batches of generic Bacitracin developed with ██████ API, Akorn prepared an ANDA, the formal, written application necessary to obtain approval from the FDA to market and sell Bacitracin in the U.S. Per FDA requirements, the ANDA was drafted to include the LOA that Akorn received from ██████ allowing Akorn to reference ██████ sterile Bacitracin API. However, due to the low market price of Bacitracin relative to the costs of production at the time, Akorn made the commercial decision not to enter the Bacitracin market at the time, and therefore chose not to submit its ANDA for FDA approval.

24. Nevertheless, Akorn maintained its business relationship with ██████ and the LOA remained in place. In November 2008, Akorn received a notification from ██████ that it had changed its name to ██████. At the time, ██████ provided an updated LOA for sterile Bacitracin API, which “authorise[d] Akorn ... to reference the ... Drug Master File: Bacitracin, sterile, DMF no: 013341” and “authorised [the FDA] to review the above file and utilise any detail disclosed therein, which is of interest in connection with our supply of bacitracin zinc, sterile to Akorn Aphtalmics [sic] and its product Bacitracin Ophthlamic [sic] Ointment.” (See Exhibit A, Letter from ██████ to Akorn, dated November 3, 2008.)

25. The ██████ LOA reflected the ongoing business relationship between Akorn and ██████ through which Akorn could purchase sterile API from ██████ and reference ██████ sterile Bacitracin API in any filing, communication, or submission to the FDA.

¹ Ingredient suppliers, such as ██████ submit a Drug Master File to the FDA, which summarizes the equipment, manufacturing process, and control measures used to prepare the particular ingredient (API). The supplier submits a reference letter (LOA) to the FDA on behalf of a particular manufacturer, stating that it will follow the methods in the Drug Master File for that manufacturer.

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II. Fera Purchases a Bacitracin ANDA and Contracts with Akorn to Manufacture Bacitracin.

26. Unlike Akorn, Fera has never developed a new pharmaceutical product itself or even an innovative application for an existing product. Instead, in 2009, shortly after it was founded, Fera purchased the rights to a portfolio of eight existing generic ophthalmic products, including Bacitracin. Fera acquired these products from Fougere, a division of Nycomed U.S., for a total payment of [REDACTED].

27. Lacking a manufacturing facility and the requisite expertise to produce ophthalmic ointments, Fera turned to Akorn, which provided “contract manufacturing” services to third parties in addition to its own development, manufacture, and sale of generic ointment products. On July 13, 2009, Fera and Akorn entered into a Contract Supply and Manufacturing Agreement (“CMS”) in which Akorn agreed to manufacture the ophthalmic products that Fera acquired from Fougere, including Bacitracin. (*See* Exhibit B, CMS Agreement.) The CMS had an initial seven-year term but allowed Akorn to terminate the agreement “in its sole discretion” if Fera failed to meet the CMS’s minimum annual purchase requirements. (*Id.*)

28. After the CMS, Akorn advised Fera that it wanted to use its own proprietary manufacturing method to make Bacitracin for Fera (rather than Fougere’s) because it was more efficient and effective for producing ophthalmic ointments. Fera agreed, and soon began marketing and selling Akorn-manufactured Bacitracin in the U.S. market.

29. Although a number of other companies had previously obtained FDA approval for their Bacitracin products, those companies had let their ANDAs lapse as of late 2009. Consequently, after acquiring Fougere’s Bacitracin ANDA, Fera was the only company actively marketing and selling Bacitracin in the U.S., and it exploited its market power by increasing the price of Bacitracin from a few dollars per unit to approximately \$50 per unit, an increase of more than 1,000%.

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III. Akorn Finalizes and Submits Its Bacitracin ANDA for FDA Approval.

30. The following year, Akorn decided to finalize its ANDA in anticipation of entering the Bacitracin market. On December 16, 2010, Akorn purchased sterile Bacitracin API from [REDACTED] to produce another exhibit batch of Bacitracin, a necessary step in updating Akorn's ANDA. When it made this purchase, Akorn was completely forthright with [REDACTED] explaining that it was purchasing some API for use in the Bacitracin it supplied to Fera under the CMS and some to support an "Akorn core product launch."

31. Next, Akorn finalized the ANDA it had initially prepared almost a decade prior. The ANDA expressly referenced and relied upon the LOA from [REDACTED]. On June 8, 2011, Akorn submitted its ANDA to the FDA for Bacitracin at a 500 units/gram dosage. Akorn's ANDA was assigned ANDA # 203257.

IV. Akorn Exercises Its Right to Terminate the CMS Right and Fera Commences This Lawsuit.

32. In May 2012, three years into the CMS, Akorn exercised its contractual right to terminate the CMS because Fera had failed to fulfill the minimum annual purchase quantities for the calendar year 2011. Only then did Fera take issue with Akorn's alleged conduct during the term of the CMS Agreement. Fera filed this lawsuit on September 12, 2012, contesting Akorn's termination over minimum quantities—but also asserting for the first time that it was fraudulently induced to enter into the CMS and alleging claims for breach of contract, unfair competition and trade secret misappropriation based on a panoply of alleged conduct from 2009 and early 2010.

33. Fera's lawsuit was a transparent attempt to prevent Akorn from entering the Bacitracin market. Although Akorn had developed its own Bacitracin ten years before Fera purchased Fougere's rights and even though Akorn had used its own proprietary manufacturing process to make Fera's Bacitracin during the life of the CMS Agreement (with Fera's knowledge

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and consent), Fera alleged that Akorn had misappropriated Fera's confidential information and should be enjoined from selling its own Bacitracin in the U.S. market.

V. Fera Attempts to Sell Its Portfolio of Ophthalmic Ointments but Buyers Balk

34. In July and August 2012—after Akorn lawfully terminated the CMS but shortly before Fera filed this lawsuit—Fera engaged in discussions with [REDACTED]

[REDACTED] concerning the potential sale of Fera's ophthalmic ointment portfolio to [REDACTED]

35. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

36. Astonishingly, when Fera filed this lawsuit the following month, it attempted to portray the failed [REDACTED] deal as the basis for a purported \$100 million damages claim against Akorn—even though Fera knew at the time that [REDACTED] decision not to acquire Fera had nothing to do with Akorn. In its complaint, Fera alleged that [REDACTED] spurned the acquisition

² An "Overage" is "a fixed amount of the drug substance [i.e., API] in the dosage form that is added in excess of the label claim." See Prabu Nambiar, Steven R. Koepke, and Kevin Swiss, *CMC Sections of Regulatory Filings and CMC Regulatory Compliance during Investigational and Postapproval Stages*, in FDA REGULATORY AFFAIRS 199, 208 (David Mantus & Douglas J. Pisano eds., 3rd ed. 2014).

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because of “concern[] that Akorn would begin to use Fera’s confidential and proprietary information and trade secrets to manufacture Bacitracin.” (Am. Compl. ¶¶ 63-64.) [REDACTED]

internal documents expressly refute that fallacy.

37. Fera continued its search for a suitor. [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

38. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

39.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

VI. Fera and Perrigo Conspire to Keep Competitors out of the Bacitracin Market.

40. In or around November 2012, Fera and Perrigo began discussing a potential sale of Fera's products to Perrigo.

41.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED].

42. [REDACTED]

[REDACTED]

[REDACTED]

43. [REDACTED]

[REDACTED] [REDACTED] sterile API was the only API qualified by the FDA for use in Bacitracin in the U.S. If other companies could not buy API from [REDACTED] then they could not make and sell Bacitracin in the U.S. [REDACTED]

[REDACTED]

[REDACTED]

44. [REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

45. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

³ These activities constitute “gun-jumping,” which is a violation under the Hart-Scott-Rodino Act, Section 7A of the Clayton Act, 15 U.S.C. § 18A.

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[REDACTED]

[REDACTED]

46. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

47. [REDACTED]

[REDACTED]

[REDACTED]

48. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

49. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

50. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

51. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

52. On June 14, 2013, [REDACTED] Fera
and Perrigo signed the APA. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

53. [REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

54. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

55. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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56. [REDACTED]

[REDACTED]

[REDACTED]

57. [REDACTED]

[REDACTED]

[REDACTED]

VII. Fera and Perrigo Implement Their Illegal Scheme.

58. [REDACTED]

[REDACTED]

59. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

60. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

61. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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62.

[REDACTED]

[REDACTED]

[REDACTED]

63.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

64.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

65.

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED].

66.

[REDACTED]

[REDACTED]. As a result, Akorn waited for the FDA to approve its pending ANDA, believing that it would be able to enter the market in the first quarter of 2014.

67. The FDA approved Akorn's ANDA on December 13, 2013.

68. However, as expected by Fera and Perrigo, as soon as the FDA was made aware that [REDACTED] had revoked the LOA, the FDA immediately rescinded its approval of Akorn's ANDA on February 19, 2014.

69. Without an approved ANDA, Akorn has been unable to market and sell its Bacitracin in the U.S. If Akorn's ANDA approval had not been rescinded by the FDA on February 19, 2014, Akorn would have entered the market in the first quarter of 2014.

MONOPOLY POWER AND MARKET DEFINITION

70. The relevant market is Bacitracin sold in the United States. At all relevant times, Fera/Perrigo had monopoly power over Bacitracin sold in the U.S. because they were the only holder of an FDA-approved ANDA for the drug and had the power to maintain the price of the product they sold at supracompetitive levels for a sustained period of time without losing substantial sales to any potential alternative product to Bacitracin.

71. In 2009, when Fera acquired its Bacitracin ANDA and entered the market, it unilaterally raised the price of Bacitracin from a few dollars per unit to approximately \$50 per unit, an increase of greater than 1,000%. This significant increase in the price charged did not

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result in the loss of substantial sales to any competing drug. At the time of its dramatic increase in the price of the product, Fera had a 100% market share in the Bacitracin market in the U.S., which it maintained until selling its rights to Perrigo. Since June 2013, Perrigo has possessed a 100% market share in the Bacitracin market.

72. Despite consistently charging customers supracompetitive prices, Fera was able to increase its volume of sales year-over-year. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

73. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

74. This pricing and sales data demonstrates the absence of any significant cross-elasticity of demand between Bacitracin and other ophthalmic ointments. Fera's significant increase in Bacitracin price did not prompt customers to switch to potential alternatives. Moreover, neither Fera nor Perrigo has ever lowered the price of Bacitracin in response to the pricing of other products that treat similar conditions.

75. Because of its FDA-approved labeling, Bacitracin is differentiated from other ophthalmic ointment products.

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76. Fera and Perrigo needed to control only Bacitracin, and no other products, in order to preserve their monopoly power and maintain the price of Bacitracin profitably at supracompetitive prices. Only the market entry of a competing generic Bacitracin product would render Perrigo unable to maintain the current price of Bacitracin without losing substantial sales.

77. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

78. Fera and Perrigo had, and exercised, the power to exclude and restrict competition to Bacitracin.

79. Fera and Perrigo enjoyed high barriers to entry with respect to competition to the above-defined relevant product market due to regulatory protections and the high costs of entry, which was exacerbated by Fera/Perrigo's removal of the only available API supplier.

80. The relevant geographic market is the United States, where Perrigo markets and sells Bacitracin [REDACTED]
[REDACTED], and where Akorn intended to market and sell its generic Bacitracin product. The ANDA held by Perrigo entitles it to sell Bacitracin throughout the U.S. and the product is distributed throughout the U.S. The FDA approval process permits approved drugs to be sold throughout the U.S., but does not permit non-FDA approved drugs, such as drugs approved by other countries for sale outside the U.S., from being sold in the U.S. According to data published by IMS Health, Perrigo generates greater than \$20 million in annual sales for its Bacitracin product in the U.S.

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INTERSTATE COMMERCE

81. Fera and Perrigo manufactured, promoted, distributed, and sold substantial amounts of Bacitracin in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States during the relevant period.

82. During the period of time relevant to this litigation, Fera and Perrigo sent and/or transmitted funds, contracts, invoices and business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Bacitracin.

83. In furtherance of their efforts to monopolize and restrain competition in the market for Bacitracin, Fera and Perrigo employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel.

84. The activities of Fera and Perrigo were within the flow of and have substantially affected interstate commerce.

ANTITRUST INJURY

85. Akorn has been and will continue to be injured by Fera and Perrigo's anti-competitive scheme to monopolize the generic Bacitracin market in the U.S. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The injury caused by Fera and Perrigo's actions includes lost sales volume and lost profits.

86. As a direct and proximate result of Fera and Perrigo's anti-competitive scheme, Akorn has been unable to enter the U.S. market for Bacitracin. Akorn is unable to purchase the API that is necessary to manufacture Bacitracin from [REDACTED]

[REDACTED]. Moreover, after [REDACTED] revoked Akorn's LOA, at the insistence of Fera and Perrigo

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and in furtherance of the anti-competitive scheme, Akorn's approved ANDA to market and sell Bacitracin in the U.S. was rescinded by the FDA.

87. Fera and Perrigo's anti-competitive scheme has and will continue to have an anti-competitive effect on the U.S. Bacitracin market. By foreclosing Akorn and other pharmaceutical companies from entering, Fera and Perrigo have conspired to monopolize, and monopolized, the generic Bacitracin market, prevented competitive pricing on generic Bacitracin, and charged consumers artificially inflated prices for generic Bacitracin. This harm to competition is the type of harm to which the antitrust statutes are directed.

COUNT I

**Sherman Act § 1 - Unlawful Contract, Combination, or Conspiracy in Restraint of Trade
Against Fera and Perrigo**

88. Akorn incorporates by reference paragraphs 1 through 87 as if fully set forth herein.

89. [REDACTED]
[REDACTED].

90. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

91. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

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92. [REDACTED]

93. [REDACTED]

94. [REDACTED]

95. These agreements had and will continue to have the unreasonably anti-competitive effect of monopolizing the market for generic Bacitracin in the U.S. (as there is no qualified supplier of sterile Bacitracin API other than [REDACTED] increasing the price consumers pay for generic Bacitracin.

96. As a direct and proximate result of Fera and Perrigo's agreement to monopolize the Bacitracin market, Akorn has suffered direct damages, including but not limited to, lost sales revenue stemming from Akorn's inability to market and sell its generic Bacitracin.

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COUNT II

**Sherman Act § 2 - Attempt to Monopolize, Conspiracy to Monopolize, and Monopolization
of the Market for Generic Bacitracin
Against Fera and Perrigo**

97. Akorn incorporates by reference paragraphs 1 through 96 as if fully set forth herein.

98. Fera and Perrigo have each individually attempted to monopolize, conspired to monopolize, and monopolized the market for generic Bacitracin.

99. [REDACTED]

[REDACTED]

[REDACTED]

100. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

101. [REDACTED]

[REDACTED]

[REDACTED]

102. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

REDACTED VERSION

[REDACTED]

[REDACTED].

103. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

104. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

105. These agreements had and will continue to have the unreasonably anti-competitive effect of monopolizing the market for generic Bacitracin in the U.S. (as there is no qualified supplier of sterile Bacitracin API other than [REDACTED] increasing the price consumers pay for generic Bacitracin.

106. As a direct and proximate result of Fera's and Perrigo's attempt to monopolize, conspiracy to monopolize, and monopolization of the Bacitracin market, Akorn has suffered direct damages, including but not limited to, lost sales revenue stemming from Akorn's inability to market and sell its generic Bacitracin.

REDACTED VERSION

COUNT III

**Tortious Interference with a Business Relationship
Against Fera and Perrigo**

107. Akorn incorporates by reference paragraphs 1 through 106 as if fully set forth herein.

108. Akorn and [REDACTED] had a longstanding business relationship going back to 1999. [REDACTED] provided Akorn with an LOA that allowed Akorn to utilize its Bacitracin API in the manufacture of Bacitracin and to reference [REDACTED] API in an ANDA application submitted to the FDA. Pursuant to the LOA, at various times since 1999, Akorn submitted purchase orders to [REDACTED] for the purchase of API, which were promptly filled by [REDACTED]. Akorn used the API purchased from [REDACTED] in developing its generic Bacitracin product, and Akorn referenced such API in filings, communications, and/or submissions to the FDA.

109. Akorn had an expectation of continuing to purchase API from [REDACTED] using such API in the development of its generic Bacitracin product, and referencing such API and the LOA in filings, communications, and/or submissions to the FDA.

110. Fera and Perrigo interfered with Akorn's relationship with [REDACTED] and ultimately caused [REDACTED] to terminate its relationship with Akorn. Fera and Perrigo employed illegal, dishonest, unfair, and improper means to interfere with the Akorn-[REDACTED] relationship.

111. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

112. [REDACTED]
[REDACTED]

REDACTED VERSION

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

113. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

114. Based on these actions, [REDACTED] cut off its business relationship with Akorn [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

115. [REDACTED]

[REDACTED]

[REDACTED].

116. [REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED] es.

117. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

REDACTED VERSION

[REDACTED]

[REDACTED]

[REDACTED].

118. As a result of this improper conduct, [REDACTED] withdrew its LOA to Akorn. But for the conduct of Fera and Perrigo, [REDACTED] would not have withdrawn the LOA and Akorn would have been able to purchase API from [REDACTED]. As a result of [REDACTED] withdrawal of the LOA, Akorn did not have access to Bacitracin API and the FDA rescinded approval of Akorn's Bacitracin ANDA, which rescission prevented Akorn from marketing and selling its generic Bacitracin product in the U.S.

119. As a direct and proximate result of Fera and Perrigo's intentional misrepresentations and illegal scheme to monopolize the Bacitracin market, Akorn has suffered significant damages, including but not limited to lost sales and lost revenue stemming from the FDA's rescission of Akorn's Bacitracin ANDA in an amount in excess of \$75,000.

PRAYER FOR RELIEF

WHEREFORE, Akorn demands judgment in its favor and against Fera and Perrigo as follows:

1. Injunctive relief sufficient to prevent Fera and/or Perrigo from violating the antitrust laws, or otherwise engaging in conduct designed to prevent Akorn from entering the market for generic Bacitracin, pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26;
2. An award to Akorn of actual damages in an amount to be determined at trial, trebled pursuant to Section 4 of the Clayton Act, 15 U.S.C. § 15, along with interest on such damages;
3. An award to Akorn of its costs, including reasonable attorney's fees, as provided in Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26;
4. An award to Akorn of actual damages stemming from Fera's and Perrigo's intentional and tortious misconduct, in an amount to be determined at trial;

REDACTED VERSION

5. An award to Akorn of punitive damages stemming from Fera's and Perrigo's intentional and tortious misconduct, in an amount to be determined at trial; and
6. Such further relief as the Court may deem just and equitable.

Dated: January 12, 2015

s/ John P. Del Monaco

Jay P. Lefkowitz
John P. Del Monaco
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, New York 10022
Telephone: (212) 446-4800

Douglas J. Kurtenbach
Nader R. Boulos
KIRKLAND & ELLIS LLP
300 North LaSalle
Chicago, Illinois 60654
Telephone: (312) 862-2000

Attorneys for Akorn, Inc.